



Navigate Your Regulatory Pathway with Confidence

Effectum Medical delivers expertly written reports on classification, applicable standards, and optimal approval routes — supporting both internal alignment and external fundraising.



EFFECTUM
MEDICAL

REGULATORY OPINION



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REGULATORY OPINION

Navigate Your Regulatory Pathway with Confidence

Whether you're launching a new product or entering a new market, a regulatory opinion helps you:

- Confirm classification and standards
- Choose the right regulatory pathway (EU, CH, UK, US)
- Align internally and with investors
- Prepare for MDR, IVDR, or FDA requirements

Key Benefits

- Expert analysis: Based on decades of hands-on experience
- Custom-tailored: Adjusted to your product and market
- Clarity for pitch decks & VCs: Avoid ambiguity during funding
- Applicable globally: Switzerland, EU, UK, and USA



WHAT CUSTOMERS SAY



Gian Nutal Schaedli - CEO, CompagOS AG

„Effectum Medical didn't feel like a typical consultancy; they felt like an extension of our team, an extra set of hands to help us accomplish more in less time. Their guidance gave us the confidence to establish a clear roadmap for regulatory approval, which we carried into our Venturekick Stage III pitch—and won. I would wholeheartedly recommend Effectum Medical to any startup tackling regulatory challenges.”



Uwe Sidler - Signus Medizintechnik

„From conducting a detailed needs assessment to assisting with the essential steps of setting up a subsidiary, Effectum Medical supported us in all regulatory matters, including our subsequent registration as a dealer and Swiss representative. They remained approachable at all times and were able to answer any questions that arose throughout the entire process. „



OUR SERVICES IN A NUTSHELL

Outsourced Legal Manufacturer:

Streamline market access and compliance with our trusted legal manufacturer services. Need speed? Ask about our fast-track option!

Plug & Play (e)QMS:

Accelerate your launch with a ready-made EN ISO 13485, MDR/IVDR, and FDA-compliant quality management system.

Rent an Expert:

Add quality management and regulatory expertise to your team as needed.

Regulatory Opinions:

Access expert insights for global compliance and market strategy.

AI/ML Device Certification:

Certification services for AI and machine learning-based medical devices.

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